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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,120	10/04/2004	James H. Johnson	048777/283017	4797

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EXAMINER

RAHMANI, NILOOFAR

ART UNIT PAPER NUMBER

1625

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,120	<b>Applicant(s)</b> JOHNSON ET AL.	
	<b>Examiner</b> Niloofar Rahmani	<b>Art Unit</b> 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-43 are pending in the instant application.

2. ***Priority***

This application was filed on 10/04/2004 which is a 371 of PCT/US03/10557 filed on 04/05/2003, which claims benefit of 60/370,583 filed on 04/05/2002.

3. The rejection of claims 1-43 under 35 U.S.C. 112, second paragraph for " deoxygenating the taxane" is withdrawn in view of the applicant's amendment in the paper dated on 05/08/2006.

4. The rejection of claims 16-39 under 35 U.S.C. 103(a) over US 5,319,112 is withdrawn in view of the applicant's amendment argument in the paper dated on 05/08/2006.

5. The rejection of claims 1-43 for " hindered base" under 35 U.S.C. 112, second paragraph is maintained for reason of record. Applicants argue that this term is not indefinite and specification provides sufficiently representative examples and such were well known in the art. It is the examiner's position that hindered base is vague and indefinite. There are many hindered bases. Applicant should include bases in the claims. There is no specific example in the specification to limit this definition.

6. The rejection of claim 40 under 35 U.S.C. 102(b) over US 5,679,807 is maintained for reason of record. Applicant argues that the

prior art does not disclose or suggest a method of converting an acyl protected taxane molecule comprising treating the primary amine compound with a hindered base to effect acyl migration and form another taxane molecule. In the '807 patent, the original taxane molecule may include a protecting group is removed during the second reaction, but the protecting group in the '807 patent does not migrate to another position on the taxane molecule to form another taxane molecule. It is the examiner's position that in the instant application, there is no difference in the definitions of R and R<sub>N</sub>. Furthermore, it is not clear that where the taxane molecule was deprotected. Somewhere in the reaction process the taxane molecule were deprotected at the 2' position.

7. The rejection of claims 1-43 under 35 U.S.C. 103(a) over US 5,679,807 and 5,808,113 is maintained for reason of record. Applicant argues that the prior art does not disclose or suggest a method of converting an acyl protected taxane molecule comprising treating the primary amine compound with a hindered base to effect acyl migration and form another taxane molecule. In the '807 patent, does not indicate that a protecting group originating at the 2'-O position in the first taxane molecule would result in a molecule with the same protecting group at the 3'-N position in the resulting molecule. Furthermore, '807 does not disclose or suggest an acyl group originating in the 2'-O position. It is the examiner's position that in the instant application, there is no difference

between R and R<sub>N</sub>. It is not clear that where the taxane molecule deprotected. Somewhere in there the taxane molecule were deprotected at the 2' position. Furthermore, in the prior art P can be protecting group, which includes acyl groups.

8. The rejection of claims 1-43 under 35 U.S.C. 103(a) over US 5,760,251 and WO 97/07110 is maintained for reason of record. Applicant argues that the prior art does not disclose or suggest any of the steps of "reductively deoxygenating the C-3' amide group on the taxane molecule to form an a C-3' imine compound;" "hydrolyzing the imine compound to form a primary amine compound;" and "treating the primary amine compound with a base to form another taxane molecule". It is the examiner's position that the prior art has the same starting material and the same product as the instant claims. Most steps are the same but one step is missing, so inherently should be there.

9. The rejection of claims 1-43 under 35 U.S.C. 103(a) over US 6,531,611 is maintained for reason of record. Applicant argues that the prior art does not include the same starting taxane molecule structure as the instant claims, even as an intermediary, nor does it disclose or suggest any of the process steps as the instant application. It is the examiner's position that the prior art has the same starting material (formula 8) and the same product (formula 10) as the instant claims. The prior art has inherently the same steps as the instant claims.

**10. Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way to convey reasonably to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification lacks description of the claims i.e. " hindered base". Hindered base can vary widely from OH to quinoline substituent. No information was found in the specification to limit this definition. Therefore, the specification lacks description of " hindered base".

**11. Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-43 are rejected under 35 U.S.C. 101 because the claims are inoperable. There is a missing step for deprotecting group OH in C2' position.

Thus, the claims fail to provide reaction step(s) and the operable parameter.

**12. Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-43 are rejected under 35 U.S.C. 112, first paragraph. The claims lack operable steps and parameter. The claims encompassed any and all conditions for converting a taxane molecule to another taxane molecule to deprotect the OH group in C2' position for which insufficient description was found in the specification.

**13.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on

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access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

06/28 /2006

NR



D. MARGARET SEAMAN

PRIMARY EXAMINER

GROUP 1625